K003245

DEC - 4 2000

510(K) SUMMARY

Submitted by:

Linda Coleman
Manager, Regulatory Affairs
Baxter Healthcare Corporation
I.V. Systems Division
Rte. 120 and Wilson Road
Round Lake, IL 60073

Date Prepared:
October 16, 2000

Proposed Device:

10 and 100 units/mL Heparin Lock Flush Syringe, USP

Predicate Device:

Heparin IV Flush Syringe, 10 units/mL, K990390, cleared 12/10/99
Heparin IV Flush Syringe, 100 units/mL, K990308, cleared 12/10/99

Device Description and Statement of Intended Use:

The Heparin Lock Flush Syringe, USP is a piston-type syringe filled with either 10 USP units/mL Heparin Lock Flush Solution, USP or 100 USP units/mL Heparin Lock Flush Solution, USP. The syringe has an integral male luer fitting and is covered with a tip cap closure. This device is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

Summary of Technological Characteristics of New Device to Predicate Devices

The technological features of the modified Heparin Lock Flush Syringe, 10 and 100 USP units/mL do not differ from the Heparin IV Flush Syringe, 10 and 100 USP units/mL cleared on 12/10/99 under 510(k) K990390 and 510(k) K990308, respectively. The devices have similar materials, the same product design and the same intended use.

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Discussion of Non Clinical Tests; Conclusions Drawn from Nonclinical Tests

Data were generated to assess the performance of the proposed Heparin Lock Flush Syringe, 10 and 100 USP units/mL. The data indicate that the proposed device meets all requirements.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Linda Coleman
Manager, Regulatory Affairs
Baxter Healthcare Corporation
Route 120 & Wilson Road
Round Lake, Illinois 60073-0490

Re: K003245
Trade Name: 10 and 100 units/mL Heparin Lock Flush Syringe, USA
Regulatory Class: II
Product Code: FOZ
Dated: November 17, 2000
Received: November 20, 2000

Dear Ms. Coleman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Gerald W Shipley for

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

510(k) Number: Not Available

Device Name: 10 and 100 units/mL Heparin Lock Flush Syringe, USP

Indication for Use: The Heparin Lock Flush Syringe, 10 and 100 units/mL is intended for use in flushing compatible intravenous administration sets and indwelling intravenous access devices.

Paula Cicente

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003245